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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,431	07/27/2006	**Hikaru Kai**	086039-0015	4903

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,431	KAI ET AL.	
	Examiner	Art Unit	
	AGNIESZKA BOESEN	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/11/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

The Amendment filed April 11, 2011 in response to the Office Action of December 22, 2010 is acknowledged and has been entered. Claim 1 has been amended. Claims 1-3 and 7 are pending and under examination in this Office action.

Sequence Compliance and Specification

Applicant's Sequence Listing and the amendment to the specification to recite the SEQ ID NOs filed April 11, 2011 are acknowledged.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on April 11, 2011 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

Rejection to Claims 1-3 and 7 under 35 U.S.C. 103(a) as being unpatentable over Hillegas et al.(US Patent 6,214,618 B1) in view of Ferrari et al. (US Patent 6,184,348 B1) **is withdrawn** in view of Applicant's amendment.

New Rejection necessitated by Applicant's amendment

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillegas et al.(US Patent 6,214,618 B1) in view of Ferrari et al. (US Patent 6,184,348 B1) and Aerts et al. (WO 2004/078955 A1).

Hillegas teaches methods of producing herpes virus comprising adhering cells to a microcarrier support comprising multiple copies of the cell attachment ligand the fibronectin cell binding domain, Arg Gly Asp (RGD) peptide of present SEQ ID NO: 70 (see claims 1-13, column 2, lines 19-41, column 3, lines 15-27, column 4, lines 35-62, and Example 2). The method taught by Hillegas further comprises culturing the adhesive cells in a medium free of animal origin components, subculturing the cells using the cell dispersing agent such as EDTA and trypsin and inoculating and proliferating the virus in the cells (see Figures 1-3 and Examples 1 and 2).

While Hillegas teaches Arg Gly Asp (RGD) peptide of present SEQ ID NO: 70 Hillegas does not teach the sequence of Gly Ala Gly Ala Gly Ser (GAGAGS) of present SEQ ID NO: 74. Hillegas does not teach the number-average molecular weight (Mn). Hillegas teaches EDTA and trypsin but he does not teach protease originated from a plant.

Ferrari teaches polymer polypeptides Gly Ala Gly Ala Gly Ser (GAGAGS) of present SEQ ID NO: 74 and Arg Gly Asp (RGD) peptide of present SEQ ID NO: 70 bonded together in a tandem repeat (see claims 4 and 5, and SEQ ID NO: 119 identical with present SEQ ID NO: 74). Ferrari teaches that the polymer peptide contains repeating units of Gly Ala Gly Ala Gly Ser (GAGAGS) of present SEQ ID NO: 74 and Arg Gly Asp (RGD) (see claims 1-14). Ferrari teaches molecular weight of the GAGAGS and RGD polymers from 90, 150, 250, 300, 500 to

3640 kDal (see Example 3). Ferrari teaches that the GAGAGS and RGD polypeptides are cell growth and attachment factors promoting the growth of cells in a tissue culture (Example 3).

Ferrari does not teach protease originated from a plant or a genetically recombinant bacteria.

Aerts teaches methods of producing a virus (Herpesviridae, Orthomyxovirus, Poxviridae and other) in animal-free cell culture comprising seeding the cells in cell culture medium free of animal components and letting the cells to adhere to the substrate, detaching the cells from the substrate using cell dispersing agent free from animal components such as protease originated from a plant or genetically recombinant bacteria, specifically the rProtease (Invitrogen) inoculating and proliferating the virus and growing the cells in the culture medium (see page 12, lines 26-36, page 13, lines 1-5 and 20-37, page 16, lines 10-25, page 18, lines 1-29, pages 26-27, Example 10 and claims 15-36).

It would have been prima facie obvious and one would have been motivated to provide Hillegas method of producing a virus using the microcarrier support comprising Ferrari's polymer polypeptides Gly Ala Gly Ala Gly Ser (GAGAGS) and Arg Gly Asp (RGD) because Ferrari teaches that the GAGAGS and RGD polypeptides are cell growth and attachment factors promoting the growth of cells in a tissue culture (Example 3). Absent unexpected results, it would have been prima facie obvious to provide 5 sequences of RGD peptide and 5 sequences of 3 times the GAGAGS peptide.

It would have been prima facie obvious to provide Hillegas method of producing a virus comprising subculturing the adhesive cells in Aerts' protease free of animal origin, originated from a plant or genetically recombinant bacteria because Aerts teaches to substitute the protease

free of animal origin for animal derived trypsin. Aerts teaches the use of animal free cell culture components such as animal free medium and animal free protease instead of using animal derived medium or animal derived trypsin, in order to avoid the disadvantages of animal component in a cell culture such as: batch to batch variability, the association with higher contamination risk by adventitious agents, and difficulties encountered in downstream processing such as purification (see page 2, lines 16-25).

It would have been obvious to optimize the amount and the molecular weight of the polymer polypeptides Gly Ala Gly Ala Gly Ser (GAGAGS) and Arg Gly Asp (RGD) to arrive at about 20,000 Mn. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Optimizing experimental conditions, including the amount of the compound used, falls within the skills of an ordinary artisan. If the amount of the polymer used in the claimed methods produces an unexpected result, applicant needs to point out what the unexpected results are.

All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Thus the present invention would have been prima facie obvious to the skilled artisan at the time when the invention was made.

Response to Applicant's argument

In response to Applicant's argument that neither Hillegas nor Ferrari teach the newly amended limitation of dispersing agent free of animal origin components such as protease originated from a plant, a protease originated from genetically recombinant bacteria or a combination thereof, the Examiner notes that the reference by Aerts (WO 2004/078955 A1) teaches dispersing agent free of animal origin components, a protease originated from a plant or a protease originated from genetically recombinant bacteria, and thereby cures the deficiency of Hillegas and Ferrari as discussed in the rejection above.

Conclusion

Applicant's amendment necessitated the new ground of rejections presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is (571)272-8035. The examiner can normally be reached on 9:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen/

Primary Examiner, Art Unit 1648